UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

JAMES KRAMMES AND DEBORAH, KRAMMES, h/w,	:	
Plaintiffs,	:	Civil Action No. 3:11-CV-00916
v.	:	(Judge Kosik)
ZIMMER, INC. & ZIMMER HOLDINGS, INC.,	:	
Defendants.	:	

MEMORANDUM

Before the Court are Defendants' Motion to Dismiss Plaintiffs' Second Amended Complaint (Doc. 26). For the reasons which follow, the Court will grant in part and deny in part Defendants' motion to dismiss.

I. PROCEDURAL HISTORY

On May 16, 2011, Plaintiffs filed a Complaint (Doc. 1). Defendants filed their first Motion to Dismiss (Doc. 5), on July 14, 2011. On August 16, 2011, by Order of the United States Judicial Panel on Multidistrict Ligitation, the case was transferred to the Northern District of Illinois (Doc. 13). The case was then transferred back to the Middle District of Pennsylvania on July 11, 2014 (Doc. 14). Plaintiffs filed the Amended Complaint (Doc. 23), on November 21, 2014. The Counts in the Amended Complaint include: Count I - Strict Liability (Design Defect); Count II - Strict Liability (Manufacturing Defect); Count III - Negligent Failure to Warn; Count IV - Negligent Design Defect; Count V - Negligence; Count VI - Negligent Misrepresentation; and Count VII - Loss of Consortium.

Defendants filed the instant motion to dismiss (Doc. 26), on December 22, 2014. After extensions of time were granted, the motion was briefed by both parties. On March 17, 2015, the Court heard oral argument on the motion. The motion is ripe for disposition.

II. FACTUAL BACKGROUND

The following facts are taken from Plaintiffs' Amended Complaint and are accepted as true for purposes of the instant motion. Plaintiffs allege that Defendants developed, designed, tested, manufactured, distributed, marketed and sold the Zimmer NexGen Legacy Posterior Stabalized porous femoral component with a LPS Flex articular surface ("LPS High Flex") and the NexGen Trabecular Metal MIS Stemmed Tibial component ("MIS Tibial"), of the Zimmer NexGen total knee replacement system. (Doc. 23, Second Am. Compl., at ¶ 1.) On August 1, 2008, Plaintiff James Krammes's physician, implanted a Zimmer NexGen Knee system, including a LPS High Flex, with a porous femoral component, and a MIS Tibial. (Id. at ¶ 54.)

Following the knee replacement, Mr. Krammes experienced pain and returned to his physician several times. (Id. at ¶ 57.) On or about August 24, 2009, x-rays revealed prosthetic loosening for the first time. (Id. at ¶ 58.) Mr. Krammes had a second surgery on September 30, 2009, to revise/replace the MIS Tibial and LPS High Flex, due to loosening. (Id. at ¶ 59.) During surgery, "Plaintiff's doctor discovered a lack of boney ingrowth with the femoral component, delamination of the tibia component and loosening of the posterior page." (Id.) The implant was then revised with the Zimmer NexGen Legacy Posterior Stabilized ("LPS") femur, extra stemmed length tibial component, and a LCCK spacer. (Id.) On June 23, 2010, Mr. Krammes had a third surgery to revise/replace the implant due to a possible nickel allergy. (Id. at ¶ 60.)

In December 2009, Zimmer recalled certain lots of the MIS Tibial implant because of a manufacturing defect. (Id. at ¶ 45.) It was determined that the titanium portion of the implant was separating from the trabecular metal material of the implant, which would cause the implant to delaminate and the implant become loose while in the patient. (Id.) 846 implants were affected by the recall. (Id.) On March 10, 2010, the Food and Drug Administration classified Defendants' efforts as a Class II Recall. (Id. at ¶ 47.)

III. STANDARD OF REVIEW

A motion under Rule 12(b)(6) allows the defendant to raise the defense that the plaintiff fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). Rule 8 of the Federal Rules of Civil Procedure provides that a pleading must set forth a claim for relief which contains a short and plain statement of the claim showing that the pleader is entitled to relief; the complaint must provide the defendant with fair notice of the claim. See Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). The issue in a motion to dismiss is whether the plaintiff should be entitled to offer evidence to support the claim, not whether the plaintiff will ultimately prevail. See Phillips v. Cnty. of Allegheny, 515 F. 3d 224, 232 (3d Cir. 2008) (the Rule 8 pleading standard "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element."); Nami v. Fauver, 82 F. 3d 63, 65 (3d Cir. 1996).

The onus is on the plaintiff to provide a well-drafted complaint that alleges factual support for its claims. "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555 (alteration in original

and internal citations omitted). The Court need not accept unsupported inferences, Cal. Pub. Employees Ret. Sys. v. The Chubb Corp., 394 F.3d 126, 143 (3d Cir. 2004), nor legal conclusions cast as factual allegations, Twombly, 550 U.S. at 556. Legal conclusions without factual support are not entitled to the assumption of truth. See Ashcroft v. Iqbal, 556 U.S. 662, 677-679 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not" satisfy the requirements of Rule 8).

Once the Court winnows conclusory allegations from those allegations supported by fact, which it accepts as true, the Court must engage in a common sense review of the claim to determine whether it is plausible. This is a context-specific task, for which the Court should be guided by its judicial experience. The Court must dismiss the complaint if it fails to allege enough facts "to state a claim to relief that is plausible on its face." Iqbal, 556 U.S. at 677 (quoting Twombly, 550 U.S. at 570). A "claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 677.

IV. DISCUSSION

Defendants assert several reasons why Plaintiffs' Amended Complaint should be dismissed. First, Defendants assert that Plaintiffs' non-negligence claims of strict liability fail as a matter of law. Second, Defendants argue that Plaintiffs' claim for negligent misrepresentation fails because it is insufficiently pled. Third, Defendants argue that Plaintiffs' negligent failure to warn, negligence, and negligent misrepresentation claims are barred by the learned intermediary doctrine to the extent Plaintiffs allege that Defendants negligently misrepresented or failed to warn Plaintiffs themselves or the general public. Fourth, Defendants argue that Plaintiffs' claims

for negligent failure to warn, negligent design defect, and negligence are duplicative and fail to state a claim of negligent design defect. Lastly, Defendants argue that Plaintiffs' claim for punitive damages fails because Plaintiffs have not alleged the requisite "outrageous conduct."

A. Non-Negligence Claims (Counts I & II)

Defendants argue that Plaintiffs' strict liability design defect and manufacturing defect claims fail as a matter of law because manufacturers of prescription medical devices are not subject to strict liability under Pennsylvania law. Plaintiffs respond by arguing that the Pennsylvania Supreme Court in Tincher v. Omega Flex, Inc., 104 A.3d 328 (Pa. 2014), established a new dual analysis applicable to strict liability claims against manufacturers of prescription devices. Plaintiffs also argue that prescription medical devices are more similar to a car than prescription drugs, which would at least allow a strict liability manufacturing defect claim.

Pennsylvania law recognizes three types of defects that can give rise to a strict liability claim: design defect, manufacturing defect, and warning defect. Doughtery v. C.R. Bard, Civil Action No. 11-6048, 2012 WL 2940727, * 2 (M.D. Pa. July 18, 2012) (citing Phillips v. A-Best Prods. Co., 665 A.2d 1167, 1170 (Pa. 1995)). Section 402A of the Restatement (Second) of Torts "imposes strict liability for products sold 'in a defective condition unreasonably dangerous to the user or consumer.'" Doughtery, 2012 WL 2940727 at *2 (internal quotations omitted). Pennsylvania has adopted and applied comment k of section 402A to prescription drugs. See Hahn v. Richter, 543 Pa. 558 (1996) (finding that the principles set forth in comment k, denying application of strict liability, applies in failure to warn cases involving prescription drugs). Comment k limits liability for "unavoidably unsafe products." Specifically, comment k states:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

See Restatement (Second) of Torts § 402A cmt. k. Although the Pennsylvania Supreme Court has not spoken as to comment k's applicability to prescription medical devices, lower Pennsylvania courts and federal courts have applied comment k to prescription medical devices. See Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. 2006) (finding that the appellants do not cite authority to restrict Hahn or comment k to prescription drugs, and that they do not provide significant analysis of the language they do seek to apply).

Plaintiffs assert that Tincher's new dual analysis approach to strict liability claims is applicable here. Defendants respond by arguing that Tincher is inapplicable because it is not a prescription drug or device case, and does not change or overrule Lance v. Wyeth, 85 A.3d 434 (Pa. 2014), and Hahn. In Tincher, homeowners brought an action against the manufacturer of stainless steel tubing. See Tincher, 104 A.3d at 335 -36. The Tincher court held that "in

Pennsylvania, the cause of action in strict products liability requires proof, in the alternative, either of the ordinary consumer's expectations or of the risk-utility of a product." Id. at 401. The Pennsylvania Supreme Court cautiously noted that "[b]right lines and broad rules always offer a superficially enticing option. However, we cannot elevate the lull of simplicity over the balancing of interests embodied by the principles underpinning [the jurisprudence of the relevant area of law]." Id. at 406 (quoting Scampone v. Highland Park Care Ctr., LLC, 57 A.3d 582, 598 (Pa. 2012)). We agree with Defendants that Tincher did not change the existing jurisprudence concerning strict liability with respect to prescription drugs and medical devices.

Plaintiffs' alternative argument is that comment k is inapplicable to the strict liability manufacturing defect claim, since it is no different than any other case alleging a manufacturing defect in the manufacturing process affecting a certain lot. Although there is a consensus among courts that comment k applies to prescription medical devices for failure to warn and design defect claims, federal courts are split as to whether comment k applies to a manufacturing defect claim involving a prescription medical device. Compare Terrell v. Davol, Inc., Civ. Action No. 13-5074, 2014 WL 3746532, *3-5 (E.D. Pa. July 30, 2014) (predicting that after Lance, the Pennsylvania Supreme Court would apply comment k to a manufacturing defect claim of a medical device), and Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 748-50 (E.D. Pa. 2007) (finding that prescription medical devices are "unavoidably unsafe" for purposes of all strict liability claims), and Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004) (discussing Hahn and predicting that the Pennsylvania Supreme Court would equally apply comment k to prescription medical devices, as it does to prescription drugs), with Doughtery, 2012 WL 2940727, *4-6 (discussing the policy behind comment k and prescription drugs and

finding that "similar concerns about strict liability do not apply in the context of manufacturing defect claims," and finding that Pennsylvania law does not preclude a strict liability claim based on a manufacturing defect).

Defendants argue though, that recent authority suggests that there is no longer a split as to whether comment k applies to strict liability manufacturing claims involving a medical device. Defendants point out that in Terrell, the district court specifically notes the split among the district courts, and states that the decisions allowing strict liability claims when a manufacturing defect is alleged to proceed, all pre-date Lance. The Terrell court found that, since the Pennsylvania Supreme Court in Lance did not distinguish a manufacturing defect claim from its statement that they have declined to extend strict liability into the prescription drug arena, then the Pennsylvania Supreme Court would not treat a manufacturing defect claim concerning prescription medical devices, any differently. See Terrell, 2014 WL 3746532, at *5. In Lance, the plaintiff brought negligence claims against a drug manufacturer for putting "an untenably dangerous product" into the marketplace. Lance, 85 A.3d at 451. The Pennsylvania Supreme Court noted that although for policy reasons, it "declined to extend strict liability into the prescription drug arena," it did not immunize drug companies from other applicable Pennsylvania tort law. Id at 453. Additionally, the Pennsylvania Superior Court in Creazzo, after discussing Hahn, found "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." Creazzo, 903 A.2d at 31.

For these reasons, we predict that the Pennsylvania Supreme Court would apply comment k to prescription medical devices, as it is applied to prescription drugs. Therefore, we will dismiss Plaintiffs' strict liability claims.

B. Negligent Misrepresentation (Count VI)

Defendants next argue that Plaintiffs' claim for negligent misrepresentation should be dismissed because comment k also bars claims sounding in fraud, and alternatively, because Plaintiffs failed to plead the claim with particularity, as required by Rule 9(b) of the Federal Rules of Civil Procedure. Defendants argue that Plaintiffs must plead facts sufficient to place Defendants on notice of the precise misconduct at issue. Plaintiffs respond by arguing that they have made their allegations of fraud with sufficient particularity, and that if any gap exists, it is because the information involved lies solely within Defendants' possession.

Under Pennsylvania law, to prove negligent misrepresentation, a plaintiff must prove: "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." Bortz v. Noon, 729 A.2d 555, 561 (Pa. 1999) (citing Gibbs v. Ernst, 647 A.2d 882, 890 (Pa. 1994)).

Additionally, Rule 9(b) states, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The United States Court of Appeals for the Third Circuit has noted that Rule 9(b) "requires plaintiffs to plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges." Kester v. Zimmer Holdings, Inc., Civ. No. 2:10-CV-00523, 2010 WL 2696467, *12 (W.D. Pa. June 16, 2010) (quoting Seville Indus. Mach. Corp. v. Southmost Mach.

Corp., 742 F.2d 786, 791 (3d Cir. 1984)). Although allegations of time, date or place satisfy the particularity requirements, a plaintiff can also satisfy the pleading requirements by pleading with a "degree of precision or some measure of substantiation into the fraud allegation." Id. (quoting Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir. 2007)).

In this case, we find that Plaintiffs met the pleading requirements of Rule 9(b). Plaintiffs' claim of negligent misrepresentation satisfies the purpose behind Rule 9(b). The allegations contained in Count VI and the preceding paragraphs of the Amended Complaint incorporated by reference, place the Defendants on notice of the misconduct at issue. Therefore, we will not dismiss Count VI of Plaintiffs' Amended Complaint.

C. Negligence Claims (Counts III, IV, V & VI)

Defendants next argue that Plaintiffs' claims for negligent failure to warn (Count III), negligence (Count V), and negligent misrepresentation (Count VI), should be dismissed to the extent Plaintiffs allege that Defendants negligently misrepresented or failed to warn Plaintiffs themselves or the general public, due to the "learned intermediary doctrine." We agree.

It is well settled that under Pennsylvania law, the learned intermediary doctrine requires the duty to run from the manufacturer of a prescription drug to the physician, and not to the patient or general public. Kline v. Pfizer, Inc., Civ. Action No. 08-3238, 2008 WL 4787577, *3 (E.D. Pa. 2008) (citing Baldino v. Castagna, 478 A.2d 807, 812 (Pa. 1984)). "Where the manufacturer provides proper warning to a consumer's physician, it will have discharged its duty to the consumer." Bergstresser v. Bristol-Myers Squibb Co., Civ. Action No. 3:12-1464, 2013 WL 1760525, *5 (M.D. Pa. April 24, 2013).

Plaintiffs do not deny such a rule. Instead, Plaintiffs argue that they included, throughout

the Amended Complaint, allegations that Mr. Krammes's physician and other physicians, did not receiving such warnings. Therefore, to the extent Plaintiffs' negligent failure to warn, negligent misrepresentation, and negligence claims rest on allegations that Defendants failed to adequately warn Plaintiffs and the general public, these claims will be denied.

Defendants also argue that Plaintiffs' claims for negligent failure to warn, negligent design defect, and negligence, should be dismissed because they are duplicative and fail to state a claim of negligent design defect. Defendants argue that Lance v. Wyeth limits negligence claims against a pharmaceutical company, to allegations that the company breached its duty of care by entering a product into the marketplace that is "too harmful to be used by anyone." Plaintiffs respond by arguing that Lance v. Wyeth recognized a continuum of requirements that manufacturers must adhere to when putting a product on the market. We agree with the Plaintiffs.

In Lance, the Pennsylvania Supreme Court did note that, "A company which is responsible for tendering into the market a drug which it knows or should know is so dangerous that it should not be taken by anyone can be said to have violated its duty of care either in design or marketing." Lance, 85 A.3d at 458 (citing Brief for Amici Am. & Pa. Ass'ns for Justice at 3 ("[A] manufacturer's negligent conduct can occur at any stage of the marketing process: in the initial design of the drug, in the failure to investigate information about the risks the drug poses, and in its decision to continue to sell the drug despite those unreasonable risks.")). We do not believe that the Pennsylvania Supreme Court intended to limit negligence claims to only those products too dangerous to be taken by anyone. The Lance court stated, "We agree with Appellee that this entire continuum is within the scope of the general framework of the applicable duty of

care, while highlighting our disapproval of Wyeth's petition for manufacturer immunity at the most severe end of the scale." Id. at 460. Therefore, we will not dismiss Plaintiffs' claims for negligent failure to warn, negligent design defect, or negligence.

D. Punitive Damages

Lastly, Defendants argue that Plaintiffs' request for punitive damages should be dismissed because Plaintiffs fail to allege facts, that if proven, would establish that Defendants' conduct was malicious, willful, oppressive, or exhibited reckless indifference of the rights of others. We reserve this issue to be decided at a later time in these proceedings.

V. CONCLUSION

For the reasons set forth above, the Court will grant in part and deny in part, Defendants' motion to dismiss. An appropriate order will follow.